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10/724,978	12/01/2003	Scott E. Jahns	P-9091.04	1878
27581	7590	05/12/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			LAYNO, CARL HERNANDZ	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/724,978

Applicant(s)

JAHNS ET AL.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-17 and 32-49 is/are allowed.
- 6) ☒ Claim(s) 30 and 50-61 is/are rejected.
- 7) ☒ Claim(s) 18-29 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/17/04, 5/4/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for priority as a Continuation-In-Part (CIP) of Application Serial Number 10/207,725, filed July 29, 2002, now U.S. Patent Number 6,718,208, which is a CIP of Application Serial Number 09/670,441, filed September 26, 2000, now U.S. Patent Number 6,449,507, which is a CIP of Application Serial Number 09/433,323, filed November 3, 1999, now U.S. Patent Number 6,266,564, which is a Continuation of Application Serial Number 09/070,506, filed April 30, 1998, now U.S. Patent Number 6,006,134, which is a CIP of Application Serial Number 08/640,013, filed April 30, 1996, now Abandoned.

### ***Information Disclosure Statement***

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449), which were received by the Office on March 17, 2004 and on May 4, 2005.

### ***Oath/Declaration***

3. Acknowledgment is made of the receipt of applicant's declaration, which was received by the Office on June 1, 2004.

### ***Drawings***

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4. Applicant's formal drawings were received by the Office on December 1, 2003 and have been approved by the Examiner.

***Specification***

5. The disclosure is objected to because of the following informalities:

-p.1 of the specification, lines 1-2, the status of U.S Patent Application 10/207,725 should be updated to reflect the fact that it is now U.S Patent No. 6,718,208,

-p.1 of the specification, line 12, fill in the blank with the appropriate serial number, and

-p.1 of the specification, line 16, fill in the blank with the appropriate serial number.

Appropriate correction is required.

***Claim Objections***

6. Claims 18-29 and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claims 18-28 are duplicates of claims 2-12. Claim 29 is a duplicate of claim 14, and claim 31 is a duplicate of claim 16. To overcome this objection, the Examiner recommends changing the dependency in each of claims 18-29 and 31 to depend from claim 17, not claim 1.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase “the blood vessel” (line 1) has no antecedent basis. The claim dependency appears to be a typographical error. To overcome this rejection, the Examiner recommends changing the claim dependency to depend from either claim 28 or 29.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 50-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 18, and 21-28 of U.S. Patent No. 6,718,208.

Although the conflicting claims are not identical, they are not patentably distinct from each other

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because all elements of applicant's claims 50 and 51 are present in claim 17 of the '208 patent, while applicant's depending claims 52-60 read *verbatim* over claims 18 and 21-28, respectively, of the '208 patent.

11. Claims 50, 51, 53-56, and 61 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,735,471.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 21 contains details of a system including an endotracheal nerve stimulation electrode, a cardiac stimulation electrode, and a processor, which perform the functions of applicant's claimed nerve stimulator, cardiac stimulator, and "means for coordinated regulation", respectively. Additionally, claim 21 recites a drug pump capable of delivering at least one drug, which reads upon applicant's claim 51.

12. Claims 50, 57, and 61 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of U.S. Patent No. 6,735,471. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 22 contains details of a system including an endotracheal nerve stimulation electrode, a cardiac stimulation electrode, and a processor, which perform the functions of applicant's claimed nerve stimulator, cardiac stimulator, and "means for coordinated regulation", respectively. Additionally, claim 22 recites the feature of a respiratory controller for controlling a patient's respiration. This detail reads upon applicant's claim 57.

*Claim Rejections - 35 USC § 102*

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 50, 53-56, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins (US 5,203,326) or Schwartz (US 5,330,507) (both Applicant's prior art).

The Collins (US 5,203,326) patent, cited by the applicant as prior art, describes a pacing system whose components include those claimed by the applicant. Specifically, the device includes a nerve stimulator **20** (Fig.1), a cardiac stimulator in the form of a pacemaker **17**, and a microprocessor **19** for coordinating the activities of both stimulation circuits (col.7, lines 53-58).

In regard to claims 53 and 54, neural leads **21** connected to the nerve stimulator **20** would inherently have at least one nerve stimulation electrode in order to stimulate the neural tissue **9** (Fig.1).

In regard to claims 55 and 56, the pacemaker **17** is attached to both an atrial cardiac lead **12** and ventricular cardiac lead **13**, which would inherently have at least one cardiac stimulation electrode each in order to perform their stated function of stimulating both chambers of the heart.

In regard to claim 61, microprocessor **19** (Fig.1) performs the function of applicant's claimed "processor".

The Schwartz (US 5,330,507) patent, also cited by the applicant as prior art, describes an implantable vagal stimulation system (Fig.2) including the features of a nerve stimulator circuit

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126, a cardiac stimulator circuit 116, and processing circuits 100, 104, 108, and 110, which coordinate the outputs of the stimulator circuits.

In regard to claims 53 and 54, applicant's attention is directed to Fig.1 which shows vagal nerve stimulation electrodes 74 and 76.

In regard to claims 55 and 56, applicant's attention is also directed to Fig.1, which shows cardiac pacing/sensing electrodes 64, 65, 67, and 69.

In regard to claim 61, circuits 100, 104, 108, and 110 perform the function of applicant's claimed "processor".

***Allowable Subject Matter***

15. Claims 1-16 and 32-49 are allowed.

16. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 1, 17, 32, and 41 recite details of methods and systems involving a combination of different steps and elements, respectively, and in particular, the use of phrenic nerve stimulators and electrodes. The Examiner was unable to find the combination of a phrenic nerve stimulator/electrode with either vagal nerve stimulators, cardiac stimulators, or other nerve stimulators in the manner claimed by the applicant; consequently, the Examiner deems these claims and their depending claims to be allowable.



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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, reading "Carl H. Layno", is written over a horizontal line.

CARL LAYNO  
PRIMARY EXAMINER

CHL  
5/9/2006